PMA Monthly approvals from 2/1/2016 to 2/29/2016

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P120018	02/17/2016	PMAO - PMA Origi	SHARPS TERMINATOR	SHARPS TERMINATOR, LLC	Approval for the Sharps Terminator. This device is indicated for use by individuals and healthcare professionals to safely destroy 18-27 gauge needles up to 2 inches (approx. 5 cm). The device is for use in treatment settings such as treatment rooms, emergency/trauma rooms, wards, and medication rooms of Hospitals and Outpatient Clinics/Medical Offices, Dental Offices, and Clinical Laboratories.
P150004	02/11/2016	PMAO - PMA Origi	Axium Neurostimulator System	SPINAL MODULATION, INC	Approval for the Axium Spinal Modulation Neurostimulator System. This device is indicated for: spinal column stimulation via epidural and intra-spinal lead access to the dorsal root ganglion as an aid in the management of moderate to severe chronic intractable* pain of the lower limbs in adult patients with Complex Regional Pain Syndrome (CRPS) types I and II**. * Study subjects from the ACCURATE clinical study had failed to achieve adequate pain relief from at least 2 prior pharmacologic treatments from at least 2 different drug classes and continued their pharmacologic therapy during the clinical study. ** Please note that in 1994, a consensus group of pain medicine experts gathered by the International Association for the Study of Pain (IASP) reviewed diagnostic criteria and agreed to rename reflex sympathetic dystrophy (RSD) and causalgia, as complex regional pain syndrome (CRPS) types I and II, respectively.
P150005	02/24/2016	PMAO - PMA Origi	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Approval for the Blazer Open-Irrigated Ablation Catheter, when used with a Maestro 4000 Radiofrequency (RF) Controller and MetriQ Irrigation Pump, is indicated for cardiac electrophysiological mapping, delivering diagnostic pacing stimuli, and radiofrequency ablation of sustained or recurrent Type I Atrial Flutter (AFL) in patients age 18 or older.
P150022	02/12/2016	PMAO - PMA Origi	CLOSER VASCULAR SEALING SYSTEM	REX MEDICAL, L.P.	Approval for the Closer Vascular Sealing System (VSS). This device is indicated for the percutaneous closure of femoral artery access sites while reducing times to hemostasis and ambulation as compared to Performance Goals in patients who have undergone diagnostic or interventional endovascular procedures utilizing 5, 6 and 7 Fr procedural sheaths.

Total: 4

Data as of03/11/2016 02:10AM

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N970003/S184	02/05/2016	R - Real-Time Proc	ADVANTIO, INGENIO, VITALIO, FORMIO ESSENTIO, ACCOLADE, PROPONENT, AND ALTRUA 2 SUPPORTED BY LATITUDE CONSULT ONLY) (PACE	BOSTON SCIENTIFIC	Approval for software changes to the patient management system.
N970012/S105	02/04/2016	Y - 135 Review Tra	AMS 700 INFLATABLE PENILE PROSTHESIS (IPP)	BOSTON SCIENTIFIC CORP.	Approval for the implementation of a replacement injection mold, a contract molding service supplier change and a change to the outgassing process related to the collet component of the three devices.
N970012/S111	02/03/2016	Y - 135 Review Tra	AMS 700 INFLATABLE PENILE PROSTHESIS	BOSTON SCIENTIFIC CORP.	Approval for a change in supplier for poly(ethylene terephthalate) (PET) yarn resin and supplier.
P840001/S308	02/05/2016	N - Normal 180 Day	SPECIFY SURESCAN MRI 5-6-5 LEAD 65 CM, SPECIFY SURESCAN MRI 5-6-5 LEAD 90 CM, SPECIFY SURESCAN MRI 2X8 LEAD 65 CM, SPECI	MEDTRONIC INC.	Approval for the Specify SureScan MRI 5-6-5 and 2x8 surgical lead kits.
P880006/S094	02/12/2016	N - Normal 180 Day	SENSOLOG/DIALOG/ REGENCY FAMILY OF PACEMAKERS	ST. JUDE MEDICAL, INC.	Approval for Quadra Assura MP Cardiac Resynchronization Therapy devices (CRT-Ds) Models CD3269-40, CD3269-40Q, CD3369-40, CD3369-40Q, CD3369-40C, CD3369- 40QC; Quadra Allure MP Cardiac Resynchronization Therapy Pacemaker devices (CRT-Ps) Models PM3160 and PM3262; and Model 3330 Version 21.1 Software for the Model 3650 Merlin Patient Care System Programmer.
P880086/S260	02/12/2016	N - Normal 180 Day	AFFINITY/INTEGRITY/ VICTORY/ZEPHYR/ACCENT FAMILY OF PACEMAKERS	ST. JUDE MEDICAL, INC.	Approval for Quadra Assura MP Cardiac Resynchronization Therapy devices (CRT-Ds) Models CD3269-40, CD3269-40Q, CD3369-40, CD3369-40Q, CD3369-40C, CD3369- 40QC; Quadra Allure MP Cardiac Resynchronization Therapy Pacemaker devices (CRT-Ps) Models PM3160 and PM3262; and Model 3330 Version 21.1 Software for the Model 3650 Merlin Patient Care System Programmer.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P890003/S338	02/01/2016	N - Normal 180 Day	MONITOR	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for the Amplia MRI/Amplia MRI Quad CRT-D SureScan and Compia MRI/Compia MRI Quad CRT-D SureScan devices, programmer application software Model SW034 and extension of MR Conditional labeling for the Attain Ability and Attain Performa lead models as MRI SureScan labeled leads.
P890003/S344	02/05/2016	N - Normal 180 Day	PATIENT MONITOR	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for the Alert Management Feature for the CareLink Network.
P890003/S346	02/22/2016	R - Real-Time Proc	MYCARE LINK PATIENT MONITOR	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for firmware updates to the MyCareLink patient home monitor.
P910023/S361	02/12/2016	N - Normal 180 Day	ELLIPSE/FORTIFY ASSURA FAMILY OF ICD'S	St. Jude Medical	Approval for Quadra Assura MP Cardiac Resynchronization Therapy devices (CRT-Ds) Models CD3269-40, CD3269-40Q, CD3369-40, CD3369-40Q, CD3369-40C, CD3369- 40QC; Quadra Allure MP Cardiac Resynchronization Therapy Pacemaker devices (CRT-Ps) Models PM3160 and PM3262; and Model 3330 Version 21.1 Software for the Model 3650 Merlin Patient Care System Programmer.
P910066/S028	02/18/2016	S - Special CBE	OL1000, OL1000 SC AND SPINALOGIC BONE	DJO, LLC	Approval for the labeling to be in conformance with IEC 60601-1-6 ED.3.1, IEC 60601-1-2, ANSI/AAMI ES 60601-1:2005/A1:2012 and IEC 60601-11:2011.
P910073/S132	02/22/2016	N - Normal 180 Day		BOSTON SCIENTIFIC	Approval for ACUITYX4 leads and accessories.
P910077/S151	02/05/2016	R - Real-Time Proc	LATITUDE PATIENT MANAGEMENT SYSTEM, WAVE COMMUNICATOR MODEL 6290; NXT SYSTEM SEVER SOFTWARE MODEL 6460	BOSTON SCIENTIFIC	Approval for software changes to the patient management system.

P920048/S011	02/05/2016	R - Real-Time Proc	RAPID FFN FOR THE TLIIQ SYSTEM	HOLOGIC, INC.	Approval for design modifications to the cassette inner housing of your Rapid fFN test, to the pneumatic press plate used in the automated manufacturing process, and for introduction of a thickness gauge in the automated manufacturing process.
P930016/S047	02/09/2016	R - Real-Time Proc	STAR EXCIMER LASER SYSTEM	AMO MANUFACTURING USA, LLC	Approval for a back rest replacement switch for the STAR S4 IR Excimer Laser System.
P930039/S140	02/01/2016	N - Normal 180 Day	CAPSUREFIX NOVUS MRI SURESCAN	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for the Amplia MRI/Amplia MRI Quad CRT-D SureScan and Compia MRI/Compia MRI Quad CRT-D SureScan devices, programmer application software Model SW034 and extension of MR Conditional labeling for the Attain Ability and Attain Performa lead models as MRI SureScan labeled leads.
P950009/S018	02/12/2016	N - Normal 180 Day	BD FOCALPOINT SLIDE PROFILER	BD DIAGNOSTICS	Approval for the BD FocalPoint Slide Profiler with slides prepared by the BD Totalys SlidePrep.
P960009/S243	02/29/2016	R - Real-Time Proc	SYSTEM	MEDTRONIC NC.	Approval for the addition of new/updated safety information, specifically a warning for status dystonicus (for dystonia labeling) and potential adverse events, and the consolidation of therapy-wide adverse events supplemented by indication-specific labeling addenda.
P960016/S059	02/24/2016	O - Normal 180 Day	LIVEWIRE TC ABLATION CATHETER, SAFIRE	ST. JUDE MEDICAL	Approval for a manufacturing site located at Sterigenics, in Willowbrook, Illinois.
P960016/S060	02/18/2016	R - Real-Time Proc	CATHETER AND SAFIRE BI-DIRECTIONAL ABLATION CATHETER	ST. JUDE MEDICAL	Approval for software fixes and enhancements for the Ampere RF generator, including file system modifications, system log changes, and revised communication to compatible recording systems and the Cool Point Irrigation Pump.
P960040/S362	02/05/2016	R - Real-Time Proc	TELIGEN, ENERGEN, PUNCTUA, INCEPTA, ORIGEN, INOGEN, DYNAGEN, AUTOGEN ICD DEVICES	BOSTON SCIENTIFIC	Approval for software changes to the patient management system.
P970003/S170	02/12/2016	O - Normal 180 Day	VNS THERAPY SYSTEM	CYBERONICS, INC.	Approval for a manufacturing site located at Cyberonics Latam S.L.R., Edificio B49, 51 Ave 0, Zona Franca Coyol, Coyol - Alajuela, Costa Rica facility, in which the site will perform the final assembly, packaging, storing, and distribution of the Implantable Pulse Generators and the Lead Finals.
P970003/S188	02/19/2016	R - Real-Time Proc	PULSE/PULSE DUO GENERATOR-MODEL 102/102R	CYBERONICS, INC.	Approval for labeling changes being made to the Model 102/102R Technical Information Chapter of the VNS Therapy Physicians Manual involving the addition/correction of information concerning generator performance exceptions.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P970003/S189	02/26/2016	S - Special CBE	VNS THERAPY ASPIRESR GENERATOR; VNS THERAPY PROGRAMMING SOFTWARE	CYBERONICS, INC.	Approval for a labeling change to inform clinicians of modified stimulator programming parameters to enhance safety in the use of the device.
P970013/S066	02/12/2016	N - Normal 180 Day	MICRONY FAMILY OF PACEMAKERS	ST. JUDE MEDICAL, INC.	Approval for Quadra Assura MP Cardiac Resynchronization Therapy devices (CRT-Ds) Models CD3269-40, CD3269-40Q, CD3369-40, CD3369-40Q, CD3369-40C, CD3369- 40QC; Quadra Allure MP Cardiac Resynchronization Therapy Pacemaker devices (CRT-Ps) Models PM3160 and PM3262; and Model 3330 Version 21.1 Software for the Model 3650 Merlin Patient Care System Programmer.
P970018/S030	02/12/2016	N - Normal 180 Day	BD TOTALYS SLIDEPREP	BD DIAGNOSTIC SYSTEMS	Approval for the BD Totalys SlidePrep (and use of the BD FocalPoint Slide Profiler with slides prepared by the BD Totalys SlidePrep). The devices, as modified, will be marketed under the trade names BD Totalys SlidePrep and BD FocalPoint Slide Profiler, respectively.
P970018/S032	02/12/2016	N - Normal 180 Day	BD PREPSTAIN SYSTEM	BD DIAGNOSTIC SYSTEMS	Approval for the BD Totalys MultiProcessor, a new cell enrichment system, and the BD SurePath collection vial.
P970051/S132	02/24/2016	O - Normal 180 Day	CP900 SERIES SOUND PROCESSORS	COCHLEAR AMERICAS	Approval for a manufacturing site located at Cochlear Ltd Macquarie University, 1 University Avenue, Macquarie University, NSW 2066, Australia.
P980016/S561	02/05/2016	N - Normal 180 Day	EVERA S DR,S VR XT DR, XT VE,ICD'S; MAXIMO II ICD,. PROTECTA ICD & XT ICD, SECURA ICD, VIRTUOSO II DR/VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for the Alert Management Feature for the CareLink Network.
P980016/S563	02/22/2016	R - Real-Time Proc	EVERA MRI, EVERA, MARQUIS, SECURA, MAXIMO II, INTRINSIC, PROTECTA, PROTECTA XT, VIRTUOSO II	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for firmware updates to the MyCareLink patient home monitor.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980022/S181	02/01/2016	R - Real-Time Proc	PARADIGM REAL-TIME INSULIN PUMP. PARADIGM REAL-TIME REVEL INSULIN PUMP.	MEDTRONIC MINIMED	Approval to implement a change in the material composition of the loaner pump interior paper foam tray used for packaging the pump, which is a component of the paradigm eal-time, paradigm real-time revel and MiniMed 530G Systems.
P980035/S450	02/22/2016	R - Real-Time Proc	ADAPTA, VERSA, SENSIA, ADVISA, ADVISA MRI,ENPULSE, KAPPA	MEDTRONIC INC.	Approval for firmware updates to the MyCareLink patient home monitor.
P990023/S013	02/18/2016	N - Normal 180 Day	CELLUGEL OPHTHALMIC VISCOSURGICAL DEVICE (OVD)	ALCON LABORATORIES	Approval for an alternate packaging configuration (syringe, rubber tip cap, pouch), change in the release specification for pH, and change in the release and stability specification for osmolality.
P990037/S032	02/25/2016	S - Special CBE	D-STAT FLOWABLE HEMOSTAT	VASCULAR SOLUTIONS, INC.	Approval for labeling changes to the D-Stat Flowable Hemostat Instructions for Use.
P990046/S041	02/08/2016	Y - 135 Review Tra	OPEN PIVOT HEART VALVE AND OPEN PIVOT AORTIC VALVED GRAFT	MEDTRONIC ATS MEDICAL, INC.	Approval for modification to in-process inspection.
P990046/S042	02/12/2016	R - Real-Time Proc	OPEN PIVOT HEART VALVE, OPEN PIVOT AORTIC VALVED GRAFT, OPEN PIVOT HEART VALVE-APEX, OPEN PIVOT HEART VALVE-AP360	MEDTRONIC ATS MEDICAL, INC.	Approval to implement leaflet angle design specifications, an in-process inspection for leaflet angle, and modify the magnetic resonance labeling.
P000008/S036	02/08/2016	O - Normal 180 Day	LAP-BAND ADJUSTABLE GASTRIC BANDING SYSTEM	APOLLO ENDOSURGERY INC	Approval of the following changes to the post-approval study for the device: Addition of a Canadian site, which has been operating under the larger, international HERO study protocol.
P000029/S080	02/23/2016	O - Normal 180 Day	DEFLUX INJECTABLE GEL	VALEANT PHARMACEUTICALS NORTH AMERICA, LLC	Approval for modifications to Deflux labeling to reflect the findings of the post-approval study (PAS).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P000039/S053	02/24/2016	O - Normal 180 Day	AMPLATZER SEPTAL OCCLUDER	AGA MEDICAL CORP.	Approval for a manufacturing site located at Sterigenics, in Willowbrook, Illinois.
P000053/S056	02/04/2016	Y - 135 Review Tra	AMS 800 URINARY CONTROL SYSTEM (AUS)	BOSTON SCIENTIFIC CORP.	Approval for the implementation of a replacement injection mold, a contract molding service supplier change and a change to the outgassing process related to the collet component of the three devices.
P010012/S398	02/22/2016	N - Normal 180 Day	ACUITY X4 STRAIGHT (4671,4672), SPIRAL S (4674,4675), SPIRAL L (4677,4678) LEADS; SUTURELESS SLEEVE & FLUSHING TOOL/WIRE	BOSTON SCIENTIFIC CORP.	Approval for ACUITY X4 leads and accessories.
P010012/S408	02/05/2016	R - Real-Time Proc	COGNIS, ENERGEN, PUNCTUA, INCEPTA, ORIGEN, INOGEN, DYNAGEN, AUTOGEN, CRT-D RESYNCHRONIZATION DEVICES	BOSTON SCIENTIFIC CORP.	Approval for software changes to the patient management system.
P010015/S288	02/22/2016	R - Real-Time Proc	CONSULTA CRT-P, SYNCRA CRT-P, VIVA CRT-P	MEDTRONIC INC.	Approval for firmware updates to the MyCareLink patient home monitor.
P010020/S029	02/04/2016	Y - 135 Review Tra	AMS ACTICON NEOSPHINCTER ARTIFICIAL BOWEL SPHINCTER (ABS)	BOSTON SCIENTIFIC CORP.	Approval for the implementation of a replacement injection mold, a contract molding service supplier change and a change to the outgassing process related to the collet component of the three devices.
P010030/S070	02/09/2016	R - Real-Time Proc	LIFEVEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Approval for modifications to the Charger/Modem power supply cable.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S513	02/01/2016	N - Normal 180 Day	AMPLIA MRI/AMPLIA MRI QUAD CRT-D SURESCAN; COMPIA MRI/COMPIA MRI QUAD CRT-D SURESCAN	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for the Amplia MRI/Amplia MRI Quad CRT-D SureScan and Compia MRI/Compia MRI Quad CRT-D SureScan devices, programmer application software Model SW034 and extension of MR Conditional labeling for the Attain Ability and Attain Performa lead models as MRI SureScan labeled leads.
P010031/S522	02/05/2016	N - Normal 180 Day	BRAVA, BRAVA QUAD, CONCERTO II, CONSULTA, MAXIMO II, PROTECTA, PROTECTA XT, VIVA QUAD C, S AND XT, VIVA S, VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for the Alert Management Feature for the CareLink Network.
P010031/S524	02/22/2016	R - Real-Time Proc	VIVA, BRAVA, PROTECTA, PROTECTA XT, CONCERTO, CONCERTO II, CONSULTA, MAXIMO II, INSYNC II PROTECT	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for firmware updates to the MyCareLink patient home monitor.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P020004/S123	02/29/2016	P - Panel Track	GORE EXCLUDER ILIAC BRANCH ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Approval for the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE Device). This device is indicated for use with the GORE® EXCLUDER® AAA Endoprosthesis to isolate the common iliac artery from systemic blood flow and preserve blood flow in the external iliac and internal iliac arteries in patients with a common iliac or aortoiliac aneurysm, who have appropriate anatomy, including: 1) Adequate iliac/ femoral access; 2) Minimum common iliac diameter of 17 mm at the proximal implantation zone of the IBE; 3) External iliac artery treatment diameter range of 6.5 25 mm and seal zone length of at least 10 mm; 4) Internal iliac artery treatment diameter range of 6.5 13.5 mm and seal zone length of at least 10 mm; and 5) Adequate length from the lowest major renal artery to the internal iliac artery to accommodate the total endoprosthesis length, calculated by adding the minimum lengths of required components, taking into account appropriate overlaps between components.
P020024/S042	02/24/2016	O - Normal 180 Day	AMPLATZER DUCT OCCLUDER, AMPLATZER DUCT OCCLUDER II,	AGA MEDICAL CORP.	Approval for a manufacturing site located at Sterigenics, in Willowbrook, Illinois.
P020025/S077	02/24/2016	N - Normal 180 Day	INTELLANAV XP TEMPERATURE ABLATION CATHETER, INTELLANAV MIFI XP TEMPERATURE ABLATION CATHETER, INTELLANAV ABLATION CATHE	BOSTON SCIENTIFIC	Approval for design changes to incorporate a magnetic sensor into the IntellaTip XP and MiFi XP Temperature Ablation Catheters. The device, as modified, will be marketed under the trade name IntellaNav Xp Temperature Ablation Catheter and IntellaNav MiFi XP Temperature Ablation Catheter.
P030002/S036	02/17/2016	R - Real-Time Proc	TRULIGN TORIC WEB BASED TORIC CALCULATOR	BAUSCH & LOMB, INC.	Approval for software changes to the web-based toric calculator (WBTC) used with the Trulign Toric IOL.
P030002/S037	02/09/2016	O - Normal 180 Day	CRYSTALENS AND TRULIGN TORIC POSTERIOR CHAMBER INTRAOCULAR LENS	BAUSCH & LOMB, INC.	Approval of the following changes to the post-approval study for the device: administrative changes, including changes to personnel and organization and changes to the informed consent form.
P030005/S131	02/05/2016	R - Real-Time Proc	INVIVE, INTUA, VISIONIST, VALITUDE CRT-P RESYNCHRONIZATION DEVICES	GUIDANT CORP.	Approval for software changes to the patient management system.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030011/S038	02/22/2016	Y - 135 Review Tra	SYNCARDIA TEMPORARY TOTAL ARTIFICIAL HEART (TAH-T) SYSTEM	SYNCARDIA SYSTEMS, INC.	Approval for a location change for a secondary supplier as well as the addition of 3 new machines at the same secondary supplier.
P030019/S023	02/25/2016	S - Special CBE	ORTHOVISC	ANIKA THERAPEUTICS, INC.	Approval for adding the following language to the Instructions for Use (IFU): Intra-articular injection of sodium hyaluronate preparations has occasionally been associated with allergic/anaphylactic reactions and transient hypotension, which have generally resolved spontaneously or after conservative treatment.
P030035/S138	02/12/2016	N - Normal 180 Day	FRONTIER/FRONTIER II/ ANTHEM FAMILY OF CRT-PS	ST. JUDE MEDICAL, INC.	Approval for Quadra Assura MP Cardiac Resynchronization Therapy devices (CRT-Ds) Models CD3269-40, CD3269-40Q, CD3369-40, CD3369-40Q, CD3369-40C, CD3369- 40QC; Quadra Allure MP Cardiac Resynchronization Therapy Pacemaker devices (CRT-Ps) Models PM3160 and PM3262; and Model 3330 Version 21.1 Software for the Model 3650 Merlin Patient Care System Programmer.
P030053/S031	02/12/2016	O - Normal 180 Day	MEMORYGEL BREAST IMPLANT	MENTOR CORP.	Approval of the following changes to the post-approval study for the device: to enroll women with both MemoryGel and MemoryShape in a single study to address device specific and device class safety endpoints and updates to the study timeline.
P030054/S291	02/12/2016	N - Normal 180 Day	QUADRA ASSURA/UNIFY ASSURA FAMILY OF CRT-DS	St. Jude Medical	Approval for Quadra Assura MP Cardiac Resynchronization Therapy devices (CRT-Ds) Models CD3269-40, CD3269-40Q, CD3369-40, CD3369-40Q, CD3369-40C, CD3369- 40QC; Quadra Allure MP Cardiac Resynchronization Therapy Pacemaker devices (CRT-Ps) Models PM3160 and PM3262; and Model 3330 Version 21.1 Software for the Model 3650 Merlin Patient Care System Programmer.
P040014/S028	02/18/2016	R - Real-Time Proc	THERAPY ABLATION CATHETERS	IRVINE BIOMEDICAL, INC.	Approval of software fixes and enhancements for the Ampere RF generator, including file system modifications, system log changes, and revised communication to compatible recording systems and the Cool Point Irrigation Pump.
P040024/S086	02/04/2016	Y - 135 Review Tra	RESTYLANE, RESTYLANE-L, PERLANE, RESTYLANE SILK, RESTYLANE LYFT, INJECTABLE GELS.	GALDERMA LABORATORIES L.P	Approval for a change in control of the starting material (sodium hyaluronate).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040024/S086	02/04/2016	Y - 135 Review Tra	RESTYLANE, RESTYLANE-L, PERLANE, RESTYLANE SILK, RESTYLANE LYFT, INJECTABLE GELS.	Q-MED AB	Approval for a change in control of the starting material (sodium hyaluronate).
P040040/S025	02/24/2016	O - Normal 180 Day	AMPLATZER MUSCULAR VSD OCCLUDER	AGA MEDICAL CORP.	Approval for a manufacturing site located at Sterigenics, in Willowbrook, Illinois.
P040042/S033	02/18/2016	R - Real-Time Proc	THERAPY DUAL 8, THERAPY 8MM THERMISTOR, AND SAFIRE TX ABLATION CATHETERS, AND 1500T6 AND 1500T9 RF GENERATOR	IRVINE BIOMEDICAL,INC.(IBI)	Approval for software fixes and enhancements for the Ampere RF generator, including file system modifications, system log changes, and revised communication to compatible recording systems and the Cool Point Irrigation Pump.
P050028/S048	02/09/2016	R - Real-Time Proc	COBAS AMPLIPREP/COBAS TAQMAN HBV TEST, V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Approval to changes in AMPLILINK software v3.4.0.
P050037/S067	02/22/2016	R - Real-Time Proc	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval for replacing the 28 GA needle with a 27 GA needle in RADIESSE and RADIESSE (+) Lidocaine Kits, and revision to the labeling to reflect the approved 36 month expiration date for 1.5 cc fill volume.
P050052/S078	02/22/2016	R - Real-Time Proc	RADIESSE,RADIESSE (+) LIDOCAINE DERMAL FILLER	MERZ NORTH AMERICA, INC	Approval for replacing the 28 GA needle with a 27 GA needle in RADIESSE and RADIESSE (+) Lidocaine Kits, and revision to the labeling to reflect the approved 36 month expiration date for 1.5 cc fill volume.
P060019/S032	02/24/2016	O - Normal 180 Day	THERAPY COOL PATH ABLATION CATHETER AND IBI-1500T9 RF ABLATION GENERATOR	IRVINE BIOMEDICAL, INC.	Approval for a manufacturing site located at Irvine Biomedical, Inc., in Irvine, California.
P060019/S035	02/18/2016	R - Real-Time Proc	THERAPY COOL PATH, SAFIRE BLU, SAFIRE BLU SP AND THERAPY COOL PATH SP ABLATION	ST. JUDE MEDICAL	Approval for software fixes and enhancements for the Ampere RF generator, including file system modifications, system log changes, and revised communication to compatible recording systems and the Cool Point Irrigation Pump.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P060028/S013	02/12/2016	O - Normal 180 Day	MEMORYSHAPE BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Approval of the following changes to the post-approval study for the device: to enroll women with both MemoryGel and MemoryShape in a single study to address device specific and device class safety endpoints and updates to the study timeline.
P060028/S014	02/05/2016	Y - 135 Review Tra	MENTOR MEMORYSHAPE BREAST IMPLANTS	MENTOR WORLDWIDE LLC	Approval for 1) change 100291296: Update packaging processes with Alloyd Heat Sealers and Tyvek Pouch to implement the use of the Nilfisk GM80 CR Vacuum Cleaner around the heat sealers as a manufacturing aid to remove potential debris from equipment crevices; and 2) change 100248737: minor layout modifications to the gel fill area were made to increase operational efficiency.
P060030/S048	02/18/2016	N - Normal 180 Day	COBAS AMPLIPREP/COBAS TAQMAN HCV TEST V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Approval for use as an aid in the diagnosis of HCV infection.
P060030/S049	02/09/2016	R - Real-Time Proc	COBAS AMPLIPREP/ COBAS TAQMAN HCV TEST, V2.0	ROCHE MOLECULAR SYSTEMS, INC.	Approval to changes in AMPLILINK software v3.4.0.
P060040/S048	02/22/2016	Y - 135 Review Tra	THORATEC HEARTMATE II VENTRICULAR ASSIST SYSTEM (LVAS), THORATEC VENTRICULAR ASSIST DEVICE SYSTEM	THORATEC CORP.	Approval for a change in the supplier facility location for the Emergency Backup Battery and Sealed Lead Acid Battery.
P060040/S050	02/18/2016	S - Special CBE	THORATEC HEARTMATE LEFT VENTRICULAR ASSIST SYSTEM DEVICE (LVAS)	THORATEC CORP.	Approval for revisions to the labeling for the HeartMate® II Left Ventricular Assist System with Pocket Controller and HeartMate® II Left Ventricular Assist System with Pocket Controller and Mobile Power Unit (MPU).
P080006/S085	02/01/2016	N - Normal 180 Day	ATTAIN ABILITY MRI , PLUS MRI,STRAIGHT MRI SURESCAN; ATTAIN PERFORMA MRI,	MEDTRONIC INC.	Approval for the Amplia MRI/Amplia MRI Quad CRT-D SureScan and Compia MRI/Compia MRI Quad CRT-D SureScan devices, programmer application software Model SW034 and extension of MR Conditional labeling for the Attain Ability and Attain Performa lead models as MRI SureScan labeled leads.
P080009/S011	02/12/2016	R - Real-Time Proc	SEDASYS COMPUTER-ASSISTED PERSONALIZED SEDATION SYSTEM	ETHICON ENDO-SURGERY, INC.	Approval for software changes to pulse oximeter artifact mitigation period, redundant pulse oximetry signal quality advisory, allotted time for pulse oximeter synchronization (reset and return to normal operation), and the ability to select Clinician Response (manual) mode after starting treatment using automated response mode.

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P090013/S202	02/01/2016	N - Normal 180 Day	CAPSUREFIX MRI SURESCAN	MEDTRONIC INC.	Approval for the Amplia MRI/Amplia MRI Quad CRT-D SureScan and Compia MRI/Compia MRI Quad CRT-D SureScan devices, programmer application software Model SW034 and extension of MR Conditional labeling for the Attain Ability and Attain Performa lead models as MRI SureScan labeled leads.
P090013/S211	02/22/2016	R - Real-Time Proc	REVO MRI	MEDTRONIC INC.	Approval for firmware updates to the MyCareLink patient home monitor.
P090031/S006	02/25/2016	S - Special CBE	MONOVISC	ANIKA THERAPEUTICS, INC.	Approval for adding the following language to the Instructions for Use (IFU): Intra-articular injection of sodium hyaluronate preparations has occasionally been associated with allergic/anaphylactic reactions and transient hypotension, which have generally resolved spontaneously or after conservative treatment.
P100023/S123	02/16/2016	Y - 135 Review Tra	ION PACLITAXEL-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a change to add an alternate component supplier.
P100034/S014	02/09/2016	O - Normal 180 Day	NOVOCURE'S OPTUNE SYSTEM	NOVOCURE , LTD.	Approval of the following changes to the post-approval study for the device: modification to enrollment criteria.
P100047/S070	02/09/2016	Y - 135 Review Tra	HEARTWARE LEFT VENTRICULAR ASSIST SYSTEM	HEARTWARE, INC.	Approval for process changes at the internal battery supplier for HVAD controller.
P110010/S102	02/24/2016	Y - 135 Review Tra	PROMUS ELEMENT PLUS/ PROMUS PREMIER EVEROLIMUS-ELUTING PLATINUM CHROMIUM	BOSTON SCIENTIFIC CORP.	Approval for the change to the cleaning process for equipment used during drug-eluting stent manufacturing.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P110010/S116	02/16/2016	Y - 135 Review Tra	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHRONIMUM CORONARY STENT SYSTEM PROMUS PREMIER EVEROLIMUS-ELUTING PLATIN	BOSTON SCIENTIFIC CORP.	Approval for a change to add an alternate component supplier.
P110016/S024	02/24/2016	O - Normal 180 Day	FLEXABILITY ABLATION CATHETER	ST. JUDE MEDICAL, INC.	Approval for a manufacturing site located at Sterigenics, in Willowbrook, Illinois.
P110016/S027	02/18/2016	R - Real-Time Proc	THERAPY COOL PATH DUO,SAFIRE BLU DUO AND COOL PATH DUO,THERAPY COOL PATH DUO SP,SAFIRE BLU DUO SP,THERAY COOL FLEX CATHP	ST. JUDE MEDICAL, INC.	Approval for software fixes and enhancements for the Ampere RF generator, including file system modifications, system log changes, and revised communication to compatible recording systems and the Cool Point Irrigation Pump.
P110037/S024	02/09/2016	R - Real-Time Proc	COBAS AMPLIPREP/COBAS TAQMAN CYTOMEGALOVIRUS TEST	ROCHE MOLECULAR SYSTEMS, INC.	Approval to changes in AMPLILINK software v3.4.0.
P110040/S007	02/25/2016	O - Normal 180 Day	COMPLETE SE VASCULAR STENT SYSTEM	MEDTRONIC VASCULAR	Approval for updating the labeling to include the post-approval study results.
P110042/S057	02/05/2016	R - Real-Time Proc	EMBLEM (SUBCUTANEOUS ICD	Boston Scientific	Approval for software changes to the patient management system.
P120005/S042	02/05/2016	N - Normal 180 Day	DEXCOM G4 PLATINUM CONTINUOUS GLUCOSE	DEXCOM, INC.	Approval for modifications to the attachment method that secures the disposable housing to the adhesive patch of the sensor pod of the G4 PLATINUM/G5 Mobile sensor component which required modifications to the disposable h i i l t ti f i t t d h t t ki hi d h t th i ti th d Th
P120010/S061	02/22/2016	R - Real-Time Proc	MiniMed 530G System	MEDTRONIC INC.	Approval for a change to the shelf height specification for the Enlite Sensor base (part number 6015277-001). The Enlite Sensor base is a subcomponent of Enlite Sensor model MMT-7008, which is a component of the MiniMed 530G S t
P120010/S070	02/18/2016	N - Normal 180 Day	MINIMED 530G SYSTEM	MEDTRONIC INC.	Approval for replacing the Enlite Serter (MMT-7510) with the 1-Press Serter (MMT-7512), the blue charger (MMT-7705) in the current MiniLink Transmitter Kit (MMT-7725NA) with the grey charger (MMT-7715) and the use of one t ti ht t t i t d f t i th Mi iLi k T itt Kit
P120010/S074	02/01/2016	R - Real-Time Proc	MINIMED 530G INSULIN PUMP	MEDTRONIC MINIMED	Approval to implement a change in the material composition of the loaner pump interior paper foam tray used for packaging the pump, which is a component of the paradigm real-time, paradigm real-time revel and MiniMed

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130009/S047	02/16/2016	S - Special CBE	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for implementation of an additional in-process inspection of the introducer in the Edwards Expandable Introducer Sheath Set.
P130011/S002	02/09/2016	Y - 135 Review Tra	SOLO SMART STENTLESS HEART VALVE (SOLO SMART)	LIVANOVA CANADA CORP.	Approval for a change to the sterility testing of the final storage solution.
P130026/S011	02/24/2016	O - Normal 180 Day	TACTICATH QUARTZ ABLATION CATHETER	St. Jude Medical	Approval for a manufacturing site located at Sterigenics, in Willowbrook, Illinois.
P130026/S012	02/18/2016	R - Real-Time Proc	TACTICATH QUARTZ SET	St. Jude Medical	Approval for software fixes and enhancements for the Ampere RF generator, including file system modifications, system log changes, and revised communication to compatible recording systems and the Cool Point Irrigation Pump.
P130026/S015	02/19/2016	S - Special CBE	TACTICATH QUARTZ SET	St. Jude Medical	Approval for modifications to the definition of the LSI multi-parameter index in the TactiSys Quartz Instructions for Use document.
P130030/S017	02/16/2016	Y - 135 Review Tra	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC	Approval for a change to add an alternate component supplier.
P140008/S002	02/26/2016	O - Normal 180 Day	ORBERA INTRAGASTRIC BALLOON SYSTEM	APOLLO ENDOSURGE RY INC	Approval of the post-approval study protocol.
P140013/S001	02/23/2016	R - Real-Time Proc	MINERVA ENDOMETRIAL ABLATION SYSTEM	MINERVA SURGICAL	Approval for a software modification to the Minerva RF Controller software to reduce the occurrence of false error codes.

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N970003/S185	02/03/2016	X - 30-Day Notice	ESSENTIO; PROPONENT; ACCOLADE ; ALTRUA 2 PACEMAKERS	BOSTON SCIENTIFIC	Vertical integration of the manufacturing of the spring connector block housings for the devices.
P830055/S167	02/24/2016	X - 30-Day Notice	LCS TOTAL KNEE SYSTEM	DEPUY, INC.	Additional work to be performed at manual process stations and additional inspection steps.
P860003/S084	02/25/2016	X - 30-Day Notice	THERAKOS CELLEX PROCEDURAL KIT	THERAKOS, INC.	Addition of an alternate supplier for the drive tube subassembly of the CELLEX Procedural Kit.
P860004/S245	02/18/2016	X - 30-Day Notice	SYNCHROMED II PUMP	MEDTRONIC INC.	Sub-tier plating supplier change and accompanying minor manufacturing changes for the alarm spring component of the Model 8637 SynchroMed®II pump.
P860057/S141	02/10/2016	X - 30-Day Notice	CARPENTIER-EDWARDS PERIMOUNT PERICARDIAL AORTIC BIOPROSTHESIS. RSR PERICARDIAL AORTIC BIOPROSTHESIS, MAGNA PERICARDIAL A	EDWARDS LIFESCIENCES, LLC.	Modify the bioburden recovery efficiency for in-process bioburden testing.
P870076/S020	02/09/2016	X - 30-Day Notice	DISPOSABLE FALOPE-RING BANK APPLICATOR KITS	GYRUS ACMI, INC.	Change in suppliers from Senior Operations LLC (formerly known as GA MFG Precision) to C&M Machine for the manufacture of the following components of the subject device: 1) Locating Pin (part number 005267); and 2) Vercap Insert Seal Base (part number 005137).
P880086/S269	02/22/2016	X - 30-Day Notice	Victory Models 5816, 5810, 5610; Zephyr Models 5820, 5826, 5620, 5626; Accent Models PM1110, PM1210, PM2110, PM2210; Assurity Models PM1240, PM2240;	St. Jude Medical	Changes to the final electrical test equipment.

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P880086/S270	02/22/2016	X - 30-Day Notice	Assurity Models PM1240, PM2240; Assurity+ Models PM1260, PM2260; Endurity Models PM1160, PM2160; Endurity Core Models CD2275-36, CD2275-36Q, CD2311-36, CD2311-36Q, CD2411-36, CD2411-36C, CD2411-36Q, CD2411-36QC	ST. JUDE MEDICAL, INC.	Implementation of a visual inspection criterion used during the manufacturing of the hybrid assemblies.
P890040/S008	02/29/2016	X - 30-Day Notice	SOFT-FORM 55EW; LL-55; SOFTCON EW2	UNILENS CORP., USA	Increase to the sterilization load size to utilize more of the chamber capacity.
P910001/S083	02/12/2016	X - 30-Day Notice	SPECTRANETICS CVX-300 EXCIMER LASER SYSTEM	SPECTRANETICS CORP.	Change to the component manufacturing process.
P910023/S367	02/08/2016	X - 30-Day Notice	CURRENT+ FORTIFY, FORTIFY ASSURA AND ELLIPSE FAMILY OF ICD DEVICES	St. Jude Medical	Use of a new connector bore plug in the parylene coating process.
P910023/S369	02/22/2016	X - 30-Day Notice	Ellipse DR Models CD2311-36, CD2311-36Q, CD2411-36, CD2411-36Q, CD2411-36C, CD2411-36QC; Ellipse VR Models CD1311-36, CD1311-36Q, CD1411-36, CD1411-36Q, CD1411-36C, CD1411-36QC	St. Jude Medical	Changes to the foil etching process and lid lip dimension for the high voltage capacitors.
P920015/S171	02/02/2016	X - 30-Day Notice	SPRINT QUATTRO LEADS	MEDTRONIC	Change to the location of the supplier of the lead inner tray and the addition of venting channels to the inner tray package; and implementation of an automated documentation process for functional resistance testing equipment.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P920015/S172	02/01/2016	X - 30-Day Notice	SPRINT QUATTRO	MEDTRONIC	Implementation of the Leads Serial Number Generator Equipment Controller Version 4.0.0.
P920015/S173	02/09/2016	X - 30-Day Notice	SPRINT QUATTRO LEAD ; SPRINT QUATTRO LEAD	MEDTRONIC	Implementation of a peel strength test of blister packages as a process monitoring mechanism.
P930038/S079	02/29/2016	X - 30-Day Notice	ANGIO-SEAL VASCULAR CLOSURE DEVICE	ST. JUDE MEDICAL, INC.	Revised inspection requirements for the carrier tube and puncture locator components of the Angio-Seal Vascular Closure Device
P950022/S091	02/17/2016	X - 30-Day Notice	DURATA AND OPTISURE HV LEADS	St. Jude Medical	Update to the First Article Inspection procedure, an addition of pull testing of extruded tubing, a change in location for an extrusion process, and a change to the curing parameters of a polymer.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P960013/S079	02/17/2016	X - 30-Day Notice	TENDRIL SDX, ST, STS, AND OPTISCIENSE L V LEADS	PACESETTER, INC.	Update to the First Article Inspection procedure, an addition of pull testing of extruded tubing, a change in location for an extrusion process, and a change to the curing parameters of a polymer.
P960016/S061	02/29/2016	X - 30-Day Notice	LIVEWIRE(R) CARDIAC ABLATION SYSTEM	St. Jude Medical	Acceptance of an automated process for Ampere Generator region configuration.
P960030/S041	02/17/2016	X - 30-Day Notice	ISOFLEX OPTIM LV LEADS	PACESETTER, INC.	Update to the First Article Inspection procedure, an addition of pull testing of extruded tubing, a change in location for an extrusion process, and a change to the curing parameters of a polymer.
P960030/S042	02/17/2016	X - 30-Day Notice	IsoFlex Models 1642T, 1646T, 1944, 1948	PACESETTER, INC.	Add an alternate supplier for the connector pins.
P970051/S141	02/04/2016	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Introduction of a revised cleaning process for the CI24RE(CA), CI24RE(ST), and CI422 implant electronic assemblies.
P970051/S142	02/05/2016	X - 30-Day Notice	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Introduction of a pre-bake of the electronic assembly prior to pre-tinning and soldering of the implant feedthrough for the Nucleus Freedom cochlear implants.
P980016/S566	02/29/2016	X - 30-Day Notice	Evera MRI ICD DDMB1D4, DDMC3D4, DVMB1D4, DVMC3D4; Evera S DR ICD DDBC3D1, DDBC3D4; Evera S VR ICD DVBC3D1, DVBC3D4; Evera XT DR ICD DDBB1D1, DDBB1D4; Evera XT VR ICD DVBB1D1, DVBB1D4; ICD-MRI S VR SureScan Visia AF DVFC3D4; ICD-MRI VR SureScan Visia AF DVFB1D4; ICD-S VR Visia AF DVAC3D1, DVAC3D4; ICD-VR Visia AF DVAB1D1, DVAB1D4	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modifications to the battery header manufacturing process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S570	02/29/2016	X - 30-Day Notice	Evera MRI ICD DDMB1D4, DDMC3D4, DVMB1D4, DVMC3D4; Evera S DR ICD DDBC3D1, DDBC3D4; Evera S VR ICD DVBC3D1, DVBC3D4; Evera XT DR ICD DDBB1D1, DDBB1D4; Evera XT VR ICD DVBB1D1, DVBB1D4; Maximo II ICD D264DRM, D264VRM, D284VRC, D284DRG; Protecta ICD D334DRG, D334VRG, D334DRM, D334VRM; Protecta XT ICD D314DRG, D314VRG, D314DRM, D314VRM; Secura ICD D204DRM, D204VRM, D224DRG, D224VRC; Virtuoso II DR/VR ICD D274DRG, D274VRC; Visia AF MRI S VR SureScan ICD DVFC3D4; Visia AF MRI VR SureScan ICD DVFB1D4; Visia AF S VR ICD DVAC3D1, DVAC3D4; Visia AF VR ICD DVAB1D1, DVAB1D4	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modify the hybrid ionic contamination limit.
P980035/S453	02/11/2016	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG, ADVISA DR IPG, ADVISA DR MRI IPG, ADVISA SR MRI IPG, RELIA IPG	MEDTRONIC INC.	Updates to the final functional tester used at the final device assembly manufacturing facilities.
P980035/S455	02/29/2016	X - 30-Day Notice	Advisa DR IPG A4DR01; Advisa DR MRI IPG A2DR01; Advisa SR MRI IPG A3SR01	MEDTRONIC INC.	Modify the hybrid ionic contamination limit.
P980037/S055	02/10/2016	X - 30-Day Notice	ANGIOJET ULTRA XMI THROMBECTOMY SET; ANGIOJET ULTRA SPIROFLEX & SPIROFLEX VG THROMBECTOMY SET; ANGIOLET ULTRA DISTAFLEX	BOSTON SCIENTIFIC CORP.	Change to the sub-assembly manufacturing process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980037/S056	02/12/2016	X - 30-Day Notice	ANGIOJET ULTRA THROMBECTOMY SET, ANGIOJET ULTRA SPIROFLEX THROMBECTOMY, ANGIOJET ULTRA SPIROFLEX VG THROMBECTOMY, ANGIOJ	BOSTON SCIENTIFIC CORP.	Change to the component manufacturing process.
P990012/S025	02/24/2016	X - 30-Day Notice	ELECSYS HBSAG TEST SYSTEM	ROCHE DIAGNOSTICS	Relocation of manufacturing activities for processing human serum raw materials.
P010001/S015	02/25/2016	X - 30-Day Notice	TRANSCEND HIP ARTICULATION SYSTEM	CERAMTEC GMBH	Additional ultrasonic cleaning and crack detection system.
P010001/S016	02/25/2016	X - 30-Day Notice	TRANSCEND HIP ARTICULATION SYSTEM	CERAMTEC GMBH	Addition of a laser marking machine.
P010001/S017	02/24/2016	X - 30-Day Notice	TRANSCEND HIP ARTICULATION SYSTEM	CERAMTEC GMBH	Addition of one ultrasonic cleaning system.
P010015/S292	02/29/2016	X - 30-Day Notice	Consulta CRT-P C4TR01; Syncra CRT-P C2TR01	MEDTRONIC INC.	Modify the hybrid ionic contamination limit.
P010019/S044	02/23/2016	X - 30-Day Notice	LOTRAFILCON A SOFT CONTACT LENSES FOR EXTENDED WEAR	ALCON LABORATORIES, INC.	Move manufacturing of semi-finished subassemblies for the Alcon class III Lotrafilcon A Soft Contact Lens from Duluth, Georgia, USA to Johor Malaysia.
P010031/S527	02/29/2016	X - 30-Day Notice	Brava CRT-D DTBC1D4, DTBC1D1; Brava Quad CRT-D DTBC1Q1, DTBC1QQ; Viva Quad S CRT-D DTBB1Q1, DTBB1QQ, Viva Quad XT CRT-D DTBA1Q1, DTBA1QQ; Viva S CRT-D DTBB1D1, DTBB1D4, Viva XT CRT-D DTBA1D1, DTBA1D4, CRT-D MRI AMPLIA DTMB1D4, DTMB1QQ, CRT-D MRI COMPIA DTMC1D4, DTMC1QQ	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Modifications to the battery header manufacturing process.

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P010031/S529	02/29/2016	X - 30-Day Notice	Brava CRT-D DTBC1D4, DTBC1D1; Brava Quad CRTD DTBC1Q1, DTBC1QQ; Concerto II CRTD, D274TRK; Consulta CRT-D D204TRM, D224TRK; Maximo II CRT-D D264TRM, D284TRK; Protecta CRT-D D334TRM, D334TRG; Protecta XT CRTD D314TRM, D314TRG; Viva Quad S CRT-D DTBB1Q1, DTBB1QQ; Viva Quad XT CRT-D DTBA1Q1,	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEME N T	New supplier of ceramic capacitors.
P010032/S111	02/17/2016	X - 30-Day Notice	EON MINI, PROTEGE, IPG PROTEGE 3.01, IPG PROTEGE MRI	St. Jude Medical	Use of alternative batch sampling methods for bacterial endotoxin testing (BET) at the SJM Arecibo, Puerto Rico facility.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010032/S112	02/26/2016	X - 30-Day Notice	GENESIS,EON,EON C , EON MINI,PROTEGE, BRIO FAMILIES OF DEVICES	St. Jude Medical	Change to the sampling interval for bioburden and bacterial endotoxin testing of the two process water systems at the Plano, Texas manufacturing facility.
P010054/S027	02/24/2016	X - 30-Day Notice	ELECSYS ANTI-HBS TEST SYSTEM	ROCHE DIAGNOSTICS	Relocation of manufacturing activities for processing human serum raw materials.
P020004/S125	02/26/2016	X - 30-Day Notice	GORE EXCLUDER AAA ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Alternative manufacturing process for the tubular sleeves in the manufacture of the GORE EXCLUDER AAA Endoprosthesis.
P030005/S132	02/03/2016	X - 30-Day Notice	VALITUDE , VALITUDE X4 CRT-PS	BOSTON SCIENTIFIC	Vertical integration of the manufacturing of the spring connector block housings for the devices.
P030054/S297	02/08/2016	X - 30-Day Notice	PROMOTE+UNIFY, UNIFY QUADRA, UNIFY ASSURA AND QUADRA ASSURA FAMILY OF CRT-D DIVICES	St. Jude Medical	Use of a new connector bore plug in the parylene coating process.
P030054/S298	02/17/2016	X - 30-Day Notice	QUICKFLEX U AND QUARTET CRT LEADS	St. Jude Medical	Update to the First Article Inspection procedure, an addition of pull testing of extruded tubing, a change in location for an extrusion process, and a change to the curing parameters of a polymer.
P030054/S299	02/17/2016	X - 30-Day Notice	QuickFlex u Model 1258T	St. Jude Medical	Add an alternate supplier for the connector pins.
P040014/S029	02/29/2016	X - 30-Day Notice	IBI THERAPY CARDIAC ABLATION	IRVINE BIOMEDICAL, INC	Acceptance of an automated process for Ampere Generator region configuration.
P040020/S060	02/29/2016	X - 30-Day Notice	ACRYSOF MULTIFOCAL	ALCON LABORATORI ES, INC	Change to a new quality control measurement system for measuring spherical aberrations for the AcrySof® Multifocal IOL Model SN6AD1 at the Cork, Ireland manufacturing site and for the AcrySof®
P040037/S088	02/04/2016	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Use of an alternate resin in the manufacture of ePTFE fiber of the zipper component of the device, modification to raw material specification requirement and obtaining the alternate resin directly in the form
P030054/S299	02/17/2016	X - 30-Day Notice	QuickFlex u Model 1258T	St. Jude Medical	Add an alternate supplier for the connector pins.
P040014/S029	02/29/2016	X - 30-Day Notice	IBI THERAPY CARDIAC ABLATION	IRVINE BIOMEDICAL, INC	Acceptance of an automated process for Ampere Generator region configuration.
P040020/S060	02/29/2016	X - 30-Day Notice	ACRYSOF MULTIFOCAL	ALCON LABORATORI ES, INC	Change to a new quality control measurement system for measuring spherical aberrations for the AcrySof® Multifocal IOL Model SN6AD1 at the Cork, Ireland manufacturing site and for the AcrySof®
P040037/S088	02/04/2016	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Use of an alternate resin in the manufacture of ePTFE fiber of the zipper component of the device, modification to raw material specification requirement and obtaining the alternate resin directly in the form

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040043/S080	02/01/2016	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Use of a PTFE leash line fiber made from PTFE precursor tape provided by an approved supplier.
P040043/S081	02/11/2016	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Use of a new oven to process samples of the GORE TAG Thoracic Endoprosthesis for fatigue life testing.
P050006/S049	02/08/2016	X - 30-Day Notice	GORE HELEX SEPTAL OCCLUDER	W.L. GORE & ASSOCIATES,INC	Implement alternate equipment to form the delivery system mandrel.
P050010/S017	02/04/2016	X - 30-Day Notice	PRODISC-L TOTAL DISC REPLACEMENT	SYNTHES SPINE	Change in sterile package sealing pressure parameter (from 60 psi to 90 psi).
P060006/S071	02/26/2016	X - 30-Day Notice	EXPRESS SD MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Change to the terminal ethylene oxide sterilization process.
P060019/S036	02/29/2016	X - 30-Day Notice	IBI THERAPY COOL PATH ABLATION CATHETER & IBI-1500T9 RF	IRVINE BIOMEDICAL, INC.	Acceptance of an automated process for Ampere Generator region configuration.
P060040/S051	02/24/2016	X - 30-Day Notice	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORP.	Relocation of a primary supplier.
P080006/S088	02/12/2016	X - 30-Day Notice	ATTAIN ABILITY LEAD Models 4196, 4296, 4396	MEDTRONIC INC.	Addition of a new crimper system used to crimp the distal electrode component.
P080027/S022	02/20/2016	X - 30-Day Notice	ORAQUICK HCV RAPID ANTIBODY TEST	ORASURE TECHNOLOGIES INC.	Addition of a new supplier for peptides used in the manufacture of the OraQuick® HCV Rapid Antibody Test.
P090007/S014	02/24/2016	X - 30-Day Notice	ELECSYS ANTI-HCV TEST SYSTEM	ROCHE DIAGNOSTICS	Relocation of manufacturing activities for processing human serum raw materials.
P090008/S016	02/24/2016	X - 30-Day Notice	ELECSYS ANTI-HCV TEST SYSTEM	ROCHE DIAGNOSTICS	Relocation of manufacturing activities for processing human serum raw materials.

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P090009/S014	02/24/2016	X - 30-Day Notice	ELECSYS ANTI-HCV TEST SYSTEM	ROCHE DIAGNOSTICS	Relocation of manufacturing activities for processing human serum raw materials.
P090013/S217	02/29/2016	X - 30-Day Notice	Revo MRI SureScan IPG RVDR01	MEDTRONIC INC.	Modify the hybrid ionic contamination limit.
P090022/S027	02/12/2016	X - 30-Day Notice	LENSTEC SOFTEC HD POSTERIOR CHAMBER INTRAOCULAR LENS	LENSTEC, INC.	Installation of an additional steam sterilizer.
P100026/S041	02/05/2016	X - 30-Day Notice	NEUROPACE RNS SYSTEM	NEUROPACE INC	Updates/improvements to the LW5A laser welder hardware, operating software, and resulting processes.
P100031/S015	02/24/2016	X - 30-Day Notice	ELECSYS ANTI-HBC TEST SYSTEM	ROCHE DIAGNOSTICS	Relocation of manufacturing activities for processing human serum raw materials.
P100032/S012	02/24/2016	X - 30-Day Notice	ELECSYS ANTI-HBC TEST SYSTEM	ROCHE DIAGNOSTICS	Relocation of manufacturing activities for processing human serum raw materials.
P110008/S004	02/09/2016	X - 30-Day Notice	coflex Interlaminar Technology	PARADIGM SPINE, LLC	Addition of a second supplier for the instruments with the following part numbers: UAT00008, UAT00010, UAT00012, UAT00014, UAT00016, UBT10008, UBT10010, UBT10012, UBT10014, UBT10016, UAT10100, UAT10200, UAT10300, UAT20100, and UAT20110.
P110010/S119	02/26/2016	X - 30-Day Notice	PROMUS ELEMENT PLUS EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Change to the terminal ethylene oxide sterilization process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P110016/S029	02/29/2016	X - 30-Day Notice	THERAPY COOL PATH DUO/ SAFIRE BLU DUO ABLATION CATHETER AND IBI 1500T9-CP V1.6 CARDIAC ABLATION GENERATOR	ST. JUDE MEDICAL, INC.	Acceptance of an automated process for Ampere Generator region configuration.
P110022/S016	02/24/2016	X - 30-Day Notice	ELECSYS ANTI-HBC IGM TEST SYSTEM	ROCHE DIAGNOSTICS	Relocation of manufacturing activities for processing human serum raw materials.
P110025/S014	02/24/2016	X - 30-Day Notice	ELECSYS ANTI-HBC IGM TEST SYSTEM	ROCHE DIAGNOSTICS	Relocation of manufacturing activities for processing human serum raw materials.
P110031/S013	02/24/2016	X - 30-Day Notice	ELECSYS ANTI-HBC IGM TEST SYSTEM	ROCHE DIAGNOSTICS	Relocation of manufacturing activities for processing human serum raw materials.
P120016/S019	02/10/2016	X - 30-Day Notice	VASCADE VASCULAR CLOSURE SYSTEM	CARDIVA MEDICAL, INC.	Relocation of the Key Fusing subassembly to the manufacturing facility in Guayamas, Sonora, Mexico.
P130006/S027	02/04/2016	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Use of an alternate resin in the manufacture of ePTFE fiber of the zipper component of the device, modification to raw material specification requirement and obtaining the alternate resin directly in the form of precursor tapes from the existing supplier.
P130006/S028	02/18/2016	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W. L. GORE & ASSOCIATES, INC.	Changes to the manufacturing equipment.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130009/S045	02/10/2016	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Modify the bioburden recovery efficiency for in-process bioburden testing.
P130009/S048	02/16/2016	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Implement an automated data analysis spreadsheet for use during the incoming inspection for the frame tubing.
P130016/S014	02/04/2016	X - 30-Day Notice	NUCLEUS 24 HYBRID SYSTEM	COCHLEAR AMERICAS	Introduction of a revised cleaning process for the Nucleus Hybrid L24 implant electronic assemblies.
P130016/S015	02/05/2016	X - 30-Day Notice	NUCLEUS 24 HYBRID SYSTEM	COCHLEAR AMERICAS	Introduction of a pre-bake of the electronic assembly prior to pre-tinning and soldering of the implant feedthrough for the Nucleus Hybrid L24 implant.
P130017/S006	02/04/2016	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Change in test methodology for one of the incoming materials used in the Cologuard® sDNA based colorectal cancer screening test.
P130019/S007	02/12/2016	X - 30-Day Notice	MAESTRO RECHARGEABLE SYSTEM	ENTEROMEDICS INC.	Material change for the flux used during in-process rework, the use of a 10 zone Vitronics reflow oven, machine placement of the RF shield component, clarifying process instructions, and use of the alternate Mydata assembly line for the Model 2402 Mobile Charger.
P130026/S014	02/01/2016	X - 30-Day Notice	TACTICATH QUARTZ SET	St. Jude Medical	Acceptance of an alternate supplier for proximal optical fiber components and acceptance of a proposed rework process for distal optical fiber components.
P130026/S016	02/29/2016	X - 30-Day Notice	TACTICATH QUARTZ SET	St. Jude Medical	Acceptance of an automated process for Ampere Generator region configuration.
P130028/S002	02/17/2016	X - 30-Day Notice	ALGOVITA SPINAL CORD STIMULATION SYSTEM	ALGOSTIM, LLC	Alternate supplier for a component of the device battery packs.
P130030/S018	02/12/2016	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC	Change to the stent delivery catheter inspection process.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130030/S020	02/26/2016	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM (MONORAIL AND OVER-THE-WIRE)	BOSTON SCIENTIFIC	Change to the terminal ethylene oxide sterilization process.
P140009/S011	02/26/2016	X - 30-Day Notice	GENESIS,EON,EON C , EON MINI,PROTEGE, BRIO FAMILIES OF DEVICES	St. Jude Medical	Change to the sampling interval for bioburden and bacterial endotoxin testing of the two process water systems at the Plano, Texas manufacturing facility.
P140020/S005	02/18/2016	X - 30-Day Notice	BRACANALYSIS CDX DEVICE	MYRIAD GENETIC LABORATORIES	New polymerase to be used in DNA sequencing process.
P140021/S004	02/24/2016	X - 30-Day Notice	ELECSYS ANTI-HCV II TEST SYSTEM	ROCHE DIAGNOSTICS	Relocation of manufacturing activities for processing human serum raw materials.
P140031/S006	02/10/2016	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Modify the bioburden recovery efficiency for in-process bioburden testing.
P140031/S008	02/16/2016	X - 30-Day Notice	EDWARDS SAPIEN 3 TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Implement an automated data analysis spreadsheet for use during the incoming inspection for the frame tubing.
P150003/S004	02/04/2016	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIMUM CORONARY STENT SYSTEM MONORAIL & OVER-THE-WIRE.	BOSTON SCIENTIFIC CORP.	Change to the component inspection process.
P150011/S001	02/24/2016	X - 30-Day Notice	PERCEVAL SUTURELESS HEART VALVE	LIVANOVA CANADA CORP.	Changes to the sterilization process parameters and valve storage solution testing.

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